

510(k) Summary

Submitter of the Application

Midlothian Laboratories
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AUG 18 2009

Trade Name

Tropazone Lotion

Common Name

Hydrogel wound dressing

Device Classification

Hydrogel wound dressing with preservatives
Unclassified, FRO

Substantial Equivalence/ Predicate Device

Tropazone Lotion is substantially equivalent to the currently marketed devices, Mimyx cream, cleared under K041342, Zenieva cleared under K073246 and Biafine cleared under K964240.

Device Description

Tropazone Lotion is a non-sterile, semi-viscous emulsion intended for topical application. It is presented for prescription (requires a physician diagnosis of disease state) use. The product is formulated as an oil-in-water emulsion containing a polyacrylic acid polymer as the thickening agent. The oil composition of Tropazone lotion is composed of mineral oil, lecithin, fatty acids and a silicon-based organic polymer.

Intended Use of the Device

Tropazone Lotion is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. It helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Intended use is identical to that of Mimyx and Zenieva.

Table 1 - Technological Comparison

Product Name	Tropazone	MimyX	Zenievea	Biafine
510(k)	K090000	K041342	K073246	K964240
Ingredients	Purified water, liquid paraffin (mineral oil), petrolatum, alcohol, glyceryl stearate, PEG-100 stearate, paraffin, lecithin, polysorbate 60, DEA-Cetyl Phosphate, dimethicone, carbomer, imidazolidinyl urea, methylparaben, propylparaben, triethanolamine, fragrance	Purified water, olive oil, glycerin, pentylene glycol, palm glycerides, vegetable oil, hydrogenated lecithin, squalene, betaine, palmitamide MEA, sarcosine, acetamide MEA, hydroxyethyl cellulose, sodium carbomer, xanthan gum	Purified water, olive oil, glycerin, pentylene glycol, palm glycerides, vegetable oil, hydrogenated lecithin, squalene, betaine, palmitamide MEA, sarcosine, acetamide MEA, hydroxyethyl cellulose, sodium carbomer, xanthan gum	Purified water, liquid paraffin, ethylene glycol monostearate, stearic acid, propylene glycol, paraffin wax, squalene, avocado oil, trolamine/sodium alginate, triethanolamine, cetyl palmitate, methylparaben (sodium salt), sorbic acid (potassium salt), polyparaben (sodium salt) and fragrance
# applications per day	3 times per day or as needed	3 times per day or as needed	3 times per day or as needed	3 times per day
Claim	Tropazone Lotion is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. It helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.	MimyX is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. It helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.	Zenievea is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. It helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.	Biafine is for the dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, 1 st and 2 nd degree burns, including sunburns, and radiation dermatitis. When applied properly to a wound, Biafine provides an optimum moist environment for the healing process and isolates the wound from harmful germs and other external contamination.
Product Description	Water-based emulsion	Water-based emulsion	Water-based emulsion	Water-based emulsion
Physical Properties	Non-sterile white to off-white lotion	Non-sterile white to off-white thick cream	Non-sterile white to off-white thick cream	Non-sterile white to off-white thick cream

Clinical Performance Data

Tropazone when tested under occlusion may be considered a non-primary irritant and a non-primary sensitizer to skin.

Non-Clinical Performance Data

In a L929 Agar overlay cytotoxicity study using Tropazone, the cells exhibited a mild/moderate reaction.

Conclusion

Tropazone is substantially equivalent to the predicate devices listed in the table above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 18 2009

Midlothian Laboratories
% Mr. Bryce Harvey
President
760 Industrial Park Boulevard, Unit C
Montgomery, Alabama 36117

Re: K090337
Trade/Device Name: Tropazone Lotion
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 23, 2009
Received: June 24, 2009

Dear Mr. Harvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long, sweeping horizontal stroke at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090337

Indications for Use

510(k) Number (if known): K090337

Device Name: Tropazone Lotion

Indications for Use:

Tropazone Lotion is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. It helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. [Signature]
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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